



William H. Eaglstein, M.D.  
President

**IVAX Dermatologicals, Inc**

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December 12, 2005

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Office of Nutritional Products, Labeling,  
and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition, Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

**NOTIFICATION OF STATEMENTS OF NUTRITIONAL SUPPORT**

The undersigned files this notification pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(r)(6). The certification required by 21 C.F.R. § 101.93 (a)(3) is attached.

Brand Name: Heliocare®

Dietary Ingredients: Polypodium leucotomos (Calaguala) extract (leaf)

Statements of Nutritional Support:

Heliocare capsules, an oral dietary supplement with antioxidant properties which helps maintain the skin's ability to protect against sun-related effects and aging.

Fernblock™ works to protect skin structure and immune response and provides daily defense against the UV photoaging process. (Note: Fernblock™ is the standard Polypodium leucotomas extract contained in Heliocare® capsules.)

It acts as a scavenger to mop up free radicals and reactive oxygen species (ROS), particularly superoxide anions.

Inhibits formation of sunburn cells

Protects collagen by inhibiting the formation of MMP's

Protects DNA by inhibiting the formation of dimers

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LET

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Antioxidant and immune response effects

Sincerely,  
Ivax Dermatologicals, Inc.



By: William H. Eaglstein, M.D./President

Attachment - Certification



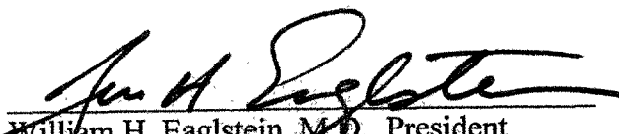
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**21 C.F.R. § 101.93(a)(3) Certification**

I certify that the information contained in the preceding section 403(r)(6) notice for Heliocare® is complete and accurate and that Ivax Dermatologicals, Inc. has substantiation that the statements are truthful and not misleading.

  
William H. Eaglstein, M.D., President  
Ivax Dermatologicals, Inc.

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